



Express Mail No. EV475142119US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of:	Kunz <i>et al.</i>	Confirmation No.:	1075
Serial No.:	09/590,002	Art Unit:	1621
Filed:	June 8, 2000	Examiner:	Samuel A. BARTS
For:	THERAPEUTIC INHIBITOR OF VASCULAR SMOOTH MUSCLE CELLS	Attorney Docket No.:	10177-216-999
		CAM No.:	008563-999213

INFORMATION DISCLOSURE STATEMENT

Mail Stop RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In accordance with the continuing duty of disclosure provisions of 37 C.F.R. §1.56, there is hereby provided certain information that the Examiner may consider material to the examination of the subject U.S. patent application. It is requested that the Examiner make this information of record if it is deemed material to the examination of the application.

The Examiner is advised that related European Patent No. 809515 was the subject of three Opposition proceedings before the Europe Patent Office and related European Patent No. 975340 was the subject of an Opposition Proceeding before the European Patent Office. Certain information relating to these proceedings and concerning coated medical devices, such as stents, was brought to Applicants' attention. The references submitted herewith include such information brought to Applicants' attention.

1. Enclosures accompanying this Information Disclosure Statement are:

- 1a. ☒ A list of all patents, publications, applications, or other information submitted for consideration by the office.
- 1b. A legible copy of :
 - ☒ Each publication or that portion which caused it to be listed on the PTO-1449;
 - ☐ For each cited pending unpublished U.S. application, the application specification including the claims, and any drawing of the application, or portion of the application which caused it to be listed on the PTO-1449 including any claims directed to that portion that have been checked to be unavailable at the USPTO's private PAIR system;
 - ☐ An English language copy of search report(s) from a counterpart foreign application or PCT International Search Report;
 - ☒ Explanations of relevancy (ATTACHMENT 1(d), hereto) or English language abstracts of the non-English language publications;
 - ☒ All other information or portion which caused it to be listed on the PTO-1449.

- 1c. ☒ Pursuant to 37 C.F.R. § 1.98(a)(2)(ii), copies of the cited U.S. patents and U.S. patent application publications are not submitted herewith unless required by the office.
- 1d. ☐ Pursuant to 1287 OG 163, copies of cited pending unpublished applications that are available at the USPTO's private PAIR system are not submitted herewith.
2. ☒ This Information Disclosure Statement is filed under 37 C.F.R. §1.97(b):
- ☐ Within three months of the filing date of a national application other than a continued prosecution application under §1.53(d);
- ☐ Within three months of the date of entry of the national stage as set forth in §1.491 in an international application;
- ☐ Before the mailing of the first Office action on the merits;
- ☒ Before the mailing of a first Office action after the filing of a request for continued examination under §1.114.
3. ☐ This Information Disclosure Statement is filed under 37 C.F.R. §1.97(c) after the period specified in 37 C.F.R. §1.97(b), but before the mailing date of any of a final action under 37 C.F.R. §1.113, a notice of allowance under 37 C.F.R. §1.311 or an action that otherwise closes prosecution in the application.

(Check either Item 3a or 3b)

- 3a. ☐ The Certification Statement in Item 5 below is applicable. Accordingly, no fee is required.
- 3b. ☐ The \$180.00 fee set forth in 37 C.F.R. §1.17(p) in accordance with 37 C.F.R. §1.97(c) is:
- ☐ enclosed.
- ☐ to be charged to Jones Day Deposit Account No. 50-3013.

(Item 3b to be checked if any reference known for more than 3 months)

4. ☐ This Information Disclosure Statement is filed under 37 C.F.R. §1.97(d) after the period specified in 37 C.F.R. §1.97(c), but on or before the date of payment of the issue fee.

The Certification Statement in Item 5 below is applicable.

The \$180.00 fee set forth in 37 C.F.R. §1.17(p) is:

- ☐ enclosed.
- ☐ to be charged to Jones Day Deposit Account No. 50-3013.
5. ☐ Certification Statement (applicable if Item 3a or Item 4 is checked):

(Check either Item 5a or 5b)

- 5a. ☐ In accordance with 37 C.F.R. §1.97(e)(1), it is certified that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.
- 5b. ☐ Each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart


application, and the communication was not **received** by any individual designated in 37 C.F.R. §1.56(c) more than thirty days prior to the filing of this information disclosure statement.

- 5c. ☐ Pursuant to 37 C.F.R. §1.704(d), each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart application, and the communication was not **received** by any individual designated in 37 C.F.R. §1.56(c) more than thirty days prior to the filing of this information disclosure statement.
6. ☒ This application is a continuation application under 37 C.F.R. §1.53(b) or (d).
(Check appropriate Items 6a, 6b and/or 6c)
- 6a. ☐ A Petition to Withdraw from issue under 37 C.F.R. §1.313(b)(5) is concurrently filed herewith.
- 6b. ☐ Copies of publications listed on Form PTO-1449 from prior application Serial No. _____, filed on _____, of which this application claims priority under 35 U.S.C. §120, are not being submitted pursuant to 37 C.F.R. §1.98(d).
- 6c. ☒ Copies of the publications listed on Form PTO-1449 were not previously cited in prior application Serial No. 08/389,712, filed on February 15, 1995, and are provided herewith.
7. ☐ This is a Supplemental Information Disclosure Statement. (Check Item 7a)
- 7a. ☐ This Supplemental Information Disclosure Statement under 37 C.F.R. §1.97(f) supplements the Information Disclosure Statement filed on _____. A bona fide attempt was made to comply with 37 C.F.R. §1.98, but inadvertent omissions were made. These omissions have been corrected herein. Accordingly, additional time is requested so that this Supplemental Information Disclosure Statement can be considered as if properly filed on _____.
8. ☐ In accordance with 37 C.F.R. §1.98, a concise explanation of what is presently understood to be the relevance of each non-English language publication is:
(Check Item 8a, 8b, or 8c)
- 8a. ☐ Satisfied because all non-English language publications were cited on the enclosed English language copy of the PCT International Search Report or the search report from a counterpart foreign application indicating the degree of relevance found by the foreign office.
- 8b. ☐ Set forth in the application.
- 8c. ☐ Enclosed as an attachment hereto.
9. ☒ The Commissioner is authorized to charge any additional fee required or credit any overpayment for this Information Disclosure Statement and/or Petition to Jones Day Deposit Account No. 50-3013.

10. ☒ No admission is made that the information cited in this Statement is, or is considered to be, material to patentability and no representation is made that a search has been made (other than a search report of a foreign counterpart application or PCT International Search Report if submitted herewith). 37 C.F.R. §§1.97(g) and (h).

Respectfully submitted,


Date: January 18, 2006



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Enclosures



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Sheet 1 of 1

LIST OF REFERENCES CITED BY APPLICANT
(Use several sheets if necessary)

ATTY. DOCKET NO.

10177-216-999

APPLICATION NO.

09/590,002

APPLICANT

Kunz *et al.*

FILING DATE

June 8, 2000

GROUP

1621

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	A01	5,342,348	08/30/94	Kaplan			
	A02	5,234,456	08/10/93	Silverstrini			
	A03						
	A04						
	A05						
	A06						
	A07						
	A08						
	A09						

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
	B01	EP 0 578 998	01/1994	Europe (with corresponding U.S. Patent No. 6,645,241)			X	
	B02	EP 0 619 314	10/12/94	Europe				
	B03	EP 0 717 041 B1	06/19/96	Europe				
	B04	EP 0 747 069	12/11/96	Europe				
	B05	WO 90/13332 A1	11/15/90	PCT				
	B06	WO 93/06792 A1	04/15/93	PCT				
	B07	WO 94/13706	06/23/94	PCT				
	B08	WO 96/03092	02/08/96	PCT				
	B09	WO 96/25176	08/22/96	PCT				

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

C01	Kirk-Othmer, Encyclopedia of Chemical Technology, 33rd edition, Vol. 17, 1982, John Wiley & Sons, pp. 281-310
C02	Langer, R., "New Methods of Drug Delivery", Science, Vol. 249, 28.09 1990, pp. 1527-1533
C03	Lipold, B.C., "Retardarzneiformen" in E. Numberg, Hagers Handbuch der pharmazeutischen Praxis, Vol. 2, Springer-Verlag Berlin Heidelberg New York, 5 th edition, 1991 pp. 832-840
C04	Tawashi, R., "The dissolution rates of crystalline drugs", J. Mond. Pharm, 4,11,1968, pp 371-379
C05	Voigt, R., Lehbuch der pharmazeutischen Technologie, 5th. edition VEB Verlag Volk und Gesundheit Berlin, 1984, p 689

EXAMINER

DATE CONSIDERED

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.